

Certificate of Analysis

Product name: Metronidazolum
Batch number / Weight: 25H21-B08-017657 / 100 g
Producer / Producer Batch Number: Wuhan Wuyao Pharmaceutical Co.,Ltd No.18 / C04-241023
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25H21-B08 / QO0025702

	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish, crystalline powder	Conform		
Identification	C	Conform		
Appearance of solution	<= ref. susp. II / <= GY6	Conform		
Related substances	Conform	Conform		
Any impurity	<= 0,1	0,01	%	
Total impurities	<= 0,2	0,02	%	
Loss on drying	<= 0,5	0,43	%	
Sulphated ash	<= 0,1	0,00	%	
Assay	99,0 - 101,0	100,48	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

16-12-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 30-9-2029

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.